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Original article

3D templating and patient-specific cutting guides (Knee-Plan®) in total knee arthroplasty: Postoperative CT-based assessment of implant positioning



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ABSTRACT

Introduction: The precision of bone cuts and the positioning of components influence the functionality and longevity of total knee arthroplasty (TKA). The objective of this study was to evaluate the results of TKA, performed after 3D preoperative templating, with the prosthesis implanted using custom cutting guides (Knee-Plan® system, Symbios Orthopédie SA).

Material and methods: This prospective study investigated 107 TKAs. Three-dimensional preoperative templating was carried out on the surface views and CT views to analyze the deformation of the lower limb and plan the implantation. The components were positioned in an individualized manner to realign the lower limb and provide ligament balance based on bone landmarks. Final component positioning was analyzed in the three planes with a postoperative CT scan. The preoperative and 1 year follow-up IKS and WOMAC scores were collected and compared.

Results: All the cutting guides were stable and functional. Femoral component planning was reproduced with 0 ± 2 precision in the frontal plane ($94\% \pm 3$), 2 ± 3 in the sagittal plane, and 0 ± 2 in the transverse plane. The precision of the tibial component was reproduced with 0 ± 2 precision in the frontal plane ($93\% \pm 3$) and 0 ± 4 in the sagittal plane. The HKA angle increased from 177 ± 7 preoperatively to 180 ± 3 at 1 year of follow-up. The IKS and WOMAC scores were significantly improved at 1 year ($P < 0.0001$).

Conclusion: The Knee-Plan® system can be a realistic, simple, and reliable alternative to conventional cutting guides and to computer-assisted surgery for TKA implantation.

Level of evidence: IV; prospective cohort study.

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1. Introduction

Frontal deviation of the mechanical axis of the lower limb beyond 3° after total knee arthroplasty (TKA) is correlated with deterioration of the clinical results and an increase in the risk of polyethylene wear, loosening, and revision over the short and long terms [1–6]. Poor rotational positioning of the femoral component is a source of pain and patellofemoral instability, and can lead to the need for revision surgery [7,8]. The stakes involved in good restoration are even higher in view of the expectations of increasingly younger and active patients, for whom the risks of revisions are greater [9]. In this context, what is referred to as

conventional instrumentation has shown its limitations [10]. Many authors have reported on the utility of intra-operative computer-assisted surgery (CAS) in guiding frontal alignment [11,12] but rarely in adjusting femoral rotation [13–15] and tibial slope [16]. In addition, CAS can lead to specific complications [17] as well as increased surgical time [18] and costs [19]. Moreover, its value in clinical terms has not been clearly demonstrated to date [20]. Over the past several years, the concept of patient-specific 3D preoperative templating and custom cutting guides has emerged, whose objectives are to guarantee precise and reproducible knee reconstruction while simplifying the surgical procedures. The results vary and few authors have made use of postoperative CT follow-up [13,14,21–26]. The objective of this study was to evaluate, using CT in three planes, the reproduction of the 3D preoperative plan with custom Knee-Plan® cutting guides (Symbios Orthopédie SA, Yverdon-les-Bains, Switzerland) and to compare them with the

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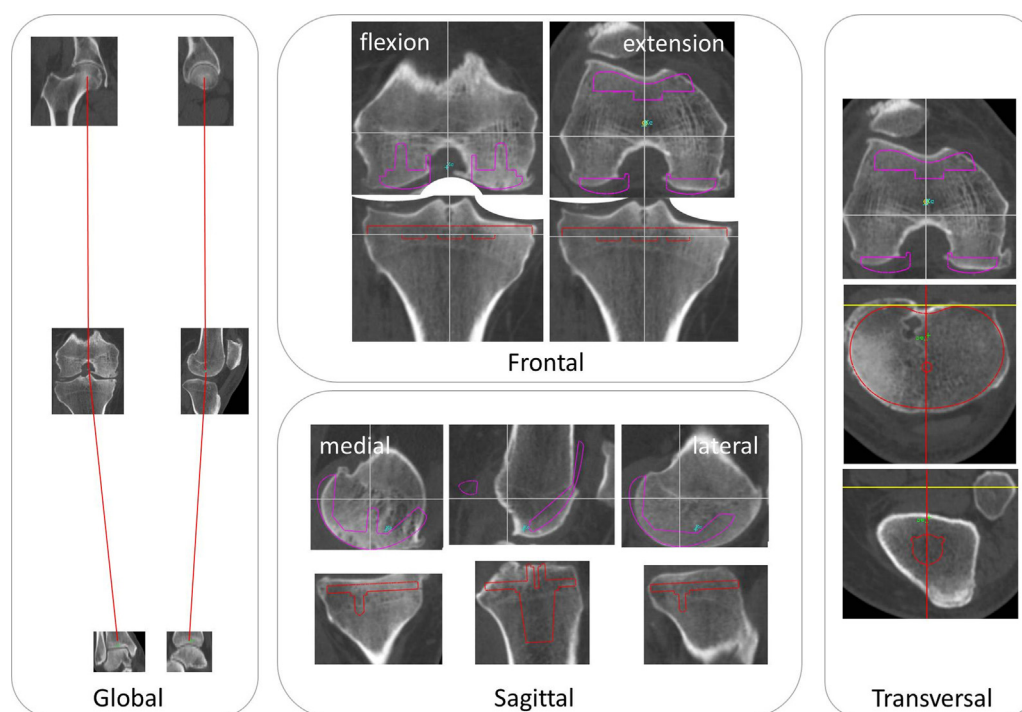


Fig. 1. Principles of Knee-Plan® patient-specific 3D preoperative templating: analysis of the overall deformity and positioning of the prosthesis components after analysis of the femoral and tibial deformities in the frontal (in flexion and extension), sagittal (medial and lateral compartments), and transverse planes.

data reported in the literature on conventional instrumentation, CAS, and other custom cutting-guide systems. We hypothesized that this technique was at least as precise as the reference methods.

2. Material and methods

2.1. Patients

This prospective single-center study investigated a consecutive series of 107 TKAs in 63 males (59%) and 44 females (41%) from September 2011 to November 2012, operated on by two senior surgeons (JPF and AS). The patients' mean age was 71.2 years (range, 43–97 years) and the mean body mass index (BMI) was 27.4 kg/m² (range, 20–43 kg/m²). The patients received a cementless ultra-congruent and posterior stabilized prosthesis with a mobile or fixed plateau (FIRST®, Symbios Orthopédie SA, Yverdon-les-Bains, Switzerland), implanted via the medial parapatellar approach. The indication was primary (91%) or post-traumatic (9%) knee osteoarthritis.

2.2. Patient-specific 3D preoperative templating

The procedure was planned using a CT combined with the Knee-Plan® software. Contrary to MRI, CT was able to identify the three centers of reference (hip, knee, and ankle) on the same acquisition. After reconstruction of the volumes and identification of the femoral and tibial mechanical axes, the preoperative plan determined the size and position of the components according to certain general principles (Fig. 1), beyond constitutional deformities. The femoral component was aligned orthogonally to the femoral mechanical axis in the frontal plane, supported by the anterolateral part of the cortical bone in the sagittal plane, and oriented along the surgical bi-epicondylar axis in the transverse plane (identified on the CT scan by a line joining the prominence of the lateral epicondyle and the sulcus on the medial epicondyle). The

tibial component was aligned orthogonally to the tibial mechanical axis in the frontal plane, along the anatomic tibial slope in the sagittal plane and the medial third of the anterior tibial tuberosity in the transverse plane. The surgical bi-epicondylar axis and the Whiteside line were the references for balancing the ligaments and the patellar tracking.

2.3. Custom cutting guides

After validation of the preoperative plan by the surgeon, the cutting guides and bone models were designed and delivered sterile (Fig. 2). The femoral and tibial bone resections were carried out after ablation of the cartilage on the contact zones, stabilization of the cutting guides with pins, and verification of cutting levels and extramedullary mechanical alignment (Fig. 3).

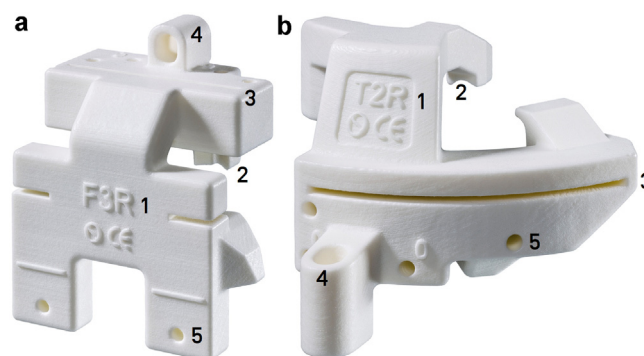


Fig. 2. View of the Knee-Plan® femoral (a) and tibial (b) cutting guides showing the size and side indications (1), the patient-specific contact zones (2), the cutting slots (3), the guidance holes of the extramedullary alignment (4), and the stabilization holes of the cutting guides with pins (5).

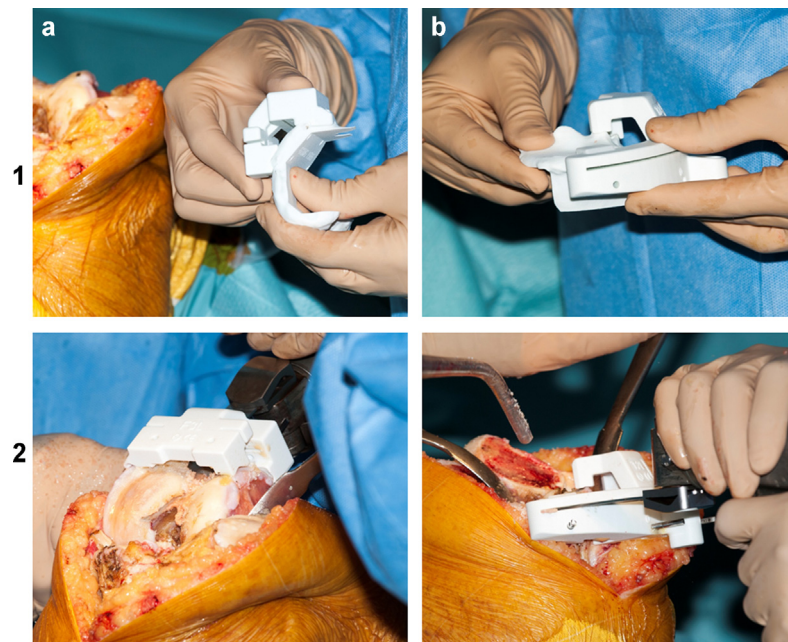


Fig. 3. Knee-Plan® surgical procedure: femoral component (a) and tibial component (b). [1: identification of weight bearing zones of the custom cutting guides on the bone models; 2: bone cuts].

2.4. Evaluation methods

The reproduction of the preoperative plan was assessed using a validated method [27] superimposing pre- and postoperative CT scans, making it possible to measure the planned position relative to the final position of the femoral and tibial components (Fig. 4). Femoral alignment was measured in the frontal plane with the mechanical femoral angle (the angle between the mechanical axis of the femur and the line tangent to the distal bicondylar surface), in the sagittal plane with the posterior distal femoral angle (the angle between the line tangent to the proximal condylar joint line and the anatomic axis of the femur), and in the transverse plane with the femoral rotation angle (the angle between the line tangent to the posterior bicondylar surface and the surgical bi-epicondylar axis). Tibial alignment was measured in the frontal plane with the mechanical tibial angle (the angle between the mechanical axis of

the tibia and the line tangent to the tibial plateaux), and in the sagittal plane with the posterior tibial slope (the angle between the line tangent to the tibial plateaux and the anatomic tibial axis). The planned and postoperative values were compared using the bilateral Student *t*-test for matched series (95% confidence interval). At 3 months and 1 year of follow-up, the clinical results were evaluated using the Knee Society score [28], quality of life with the WOMAC score [29], and the level of activity as defined by Devane et al. [30].

3. Results

All guides were stable and functional, the extramedullary verifications were all deemed satisfactory, and none of the cases required reverting to conventional instrumentation. None of the patients was lost to follow-up at 1 year of follow-up.

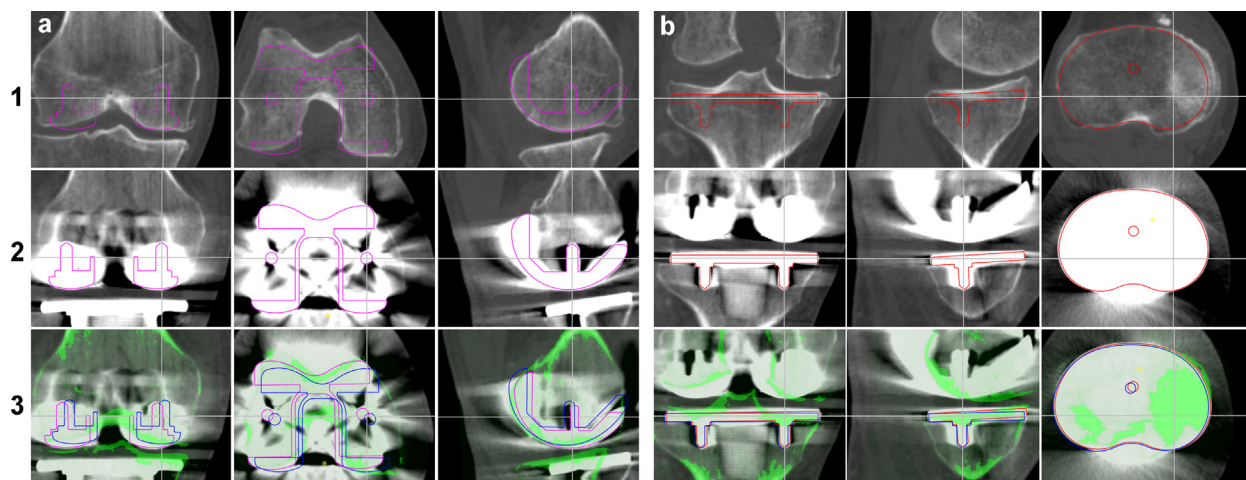


Fig. 4. Measurement method using superimposition with postoperative CT for the femoral component (a) and the tibial component (b). [1: plan; 2: postoperative CT and identification of implanted prostheses; 3: superimposition of planned implants and implanted prostheses].

Table 1
Results in terms of implant positioning.

	Preoperative	Plan	Postoperative	Δ Planned vs postoperative
<i>Femur</i>	92 ± 2 (84;98)			
Mechanical femoral angle (°) (frontal plane)		90 ± 1 (90;94)	90 ± 2 (81;95)	0 ± 2 (−9; +5)
Posterior distal femoral angle (°) (sagittal plane)		92 ± 2 (90;99)	90 ± 3 (83;101)	2 ± 3 (−7; +5)
Femoral rotation (°) (transverse plane)	92 ± 1 (90;95)	90 ± 0 (90;90)	90 ± 2 (84;98)	0 ± 2 (−6; +8)
<i>Tibia</i>				
Mechanical tibial angle (°) (frontal plane)	87 ± 4 (80;101)	90 ± 0 (90;90)	90 ± 2 (80;97)	0 ± 2 (−10; +7)
Posterior tibial slope (°) (sagittal plane)	86 ± 2 (81;90)	86 ± 2 (81;90)	87 ± 4 (77;97)	0 ± 4 (−11; +9)
HKA angle off-loaded (°)	177 ± 7 (165;195)	180 ± 1 (180;184)	180 ± 3 (172;187)	0 ± 3 (−8; +7)

±: standard deviation; (): range.

3.1. Reproduction of the preoperative plan

The size planned was identical to the size implanted in 100% of the cases for the femoral component and 96% of the cases for the tibial component. The polyethylene inserted was 10 mm thick in 87% of the cases. The position of the components in the three planes is presented in Table 1: the femoral component plan was reproduced within $\pm 3^\circ$ in 94% of the cases in the frontal plane (postoperative femoral mechanical angle, $90^\circ \pm 2$), in 71% of the cases in the sagittal plane (postoperative posterior distal femoral angle, $90^\circ \pm 3$), and in 88% of the cases in the transverse plane (postoperative femoral rotation, $0^\circ \pm 2$). The tibial component plan was reproduced within ± 3 in 93% of the cases in the frontal plane (postoperative tibial mechanical angle, $90^\circ \pm 2$) and in 70% of the cases in the sagittal plane (postoperative tibial slope, $87^\circ \pm 4$). The HKA increased from a preoperative value of $177^\circ \pm 7$ to $180^\circ \pm 3$ in the postoperative measurements. The results in the frontal plane are presented in Fig. 5.

3.2. Clinical and functional results

The clinical results in terms of quality of life and activity are presented in Table 2. None of the patients presented postoperative ligament instability.

3.3. Complications

Four cases of stiffness (3.7%) were observed: one case required changing the insert and three required arthrolysis, one of these for releasing retropatellar fibrosis. None of the femoral or tibial components required revision.

4. Discussion

Preoperative templating uses both surface views and CT slices to identify, in a reproducible fashion, the geometric variations between bone morphology and prosthetic design. The consequences of compromises made during implantation, with regards to the lower limb deformity, can thus be analyzed between the medial and lateral compartments, the distal and posterior condyles, the orientation of condyles in relation to the trochlea, and the relation between the distal femur and the proximal tibia.

To our knowledge, this study of 107 cases is the only one that has analyzed the reliability of positioning the components with this validated method superimposing pre- and postoperative CT scans. Table 3 presents the results of our series compared to the results reported in the literature, which, when postoperative results are verified with CT, MRI, or CAS, groups randomized studies comparing conventional instrumentation and CAS and studies

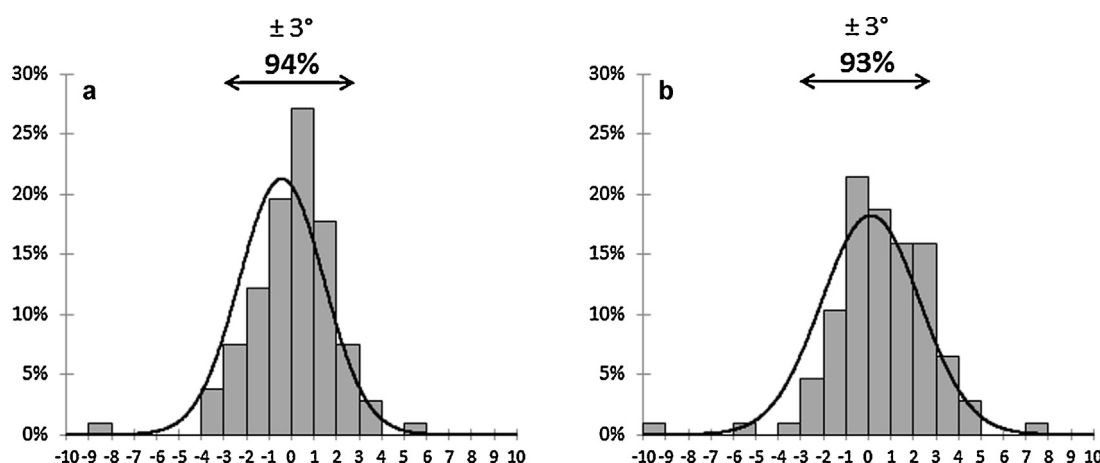


Fig. 5. Difference between plan and final frontal position of components. (a) Femoral component: difference, in degrees, between the planned femoral mechanical angle and the postoperative femoral mechanical angle. (b) Tibial component: difference, in degrees, between the planned tibial mechanical angle and the postoperative tibial angle.

Table 2

Results in clinical, quality-of-life, and activity level terms.

	Preoperative	3 months	1 year	Preoperative vs 1 year*
IKS knee score (/100)	46 ± 10 (16;64)	83 ± 14 (42;100)	91 ± 12 (48;100)	$P < 0.0001$
IKS function score (/100)	43 ± 18 (0;90)	62 ± 19 (10;90)	85 ± 20 (20;100)	$P < 0.0001$
Flexion (°)	106 ± 16 (50;150)	107 ± 16 (30;140)	117 ± 14 (90;150)	$P < 0.0001$
WOMAC score (/96)	38 ± 12 (13;74)	12 ± 9 (1;50)	5 ± 7 (0;51)	$P < 0.0001$
Devane Index (/5)	3.1 ± 0.8 (1;5)	2.8 ± 0.7 (1;5)	3.3 ± 0.7 (2;5)	$P = 0.012$

±: standard deviation; (): range.

Table 3

Literature review.

Series	Technique	Plan	Guidance	n	% of cases within ±3° compared to plan				
					Femoral varus/valgus (%)	Femoral flexion (%)	Femoral rotation (%)	Tibial varus/valgus (%)	Tibial slope (%)
Chauhan et al. [31]	Conventional instrumentation		CT	36	92	83	71	92	57
Matziolis et al. [32]			CT	28	89	–	89	82%	50
Kim et al. [33]	CAS		CT/RX	100	91	67	75	93	91
Chauhan et al. [31]			CT	35	100	89	92	100	100
Matziolis et al. [32]			CT	32	100	–	97	100	78
Kim et al. [33]			CT/RX	100	87	69	71	94	75
Conteduca et al. [21]	Visionaire®	IRM	CAS	12	100%	83	–	83	50
Heyse et al. [22]	Visionaire®	IRM	MRI	46	–	–	98	–	–
Lustig et al. [23]	Visionaire®	IRM	CAS	60	95	65	77	86	81
Roh et al. [24]	Signature®	IRM/CT	CT	50	95	90	90	100	95
Victor et al. [25]	Signature®	IRM	CT	64	93	48	77	85	79
Chareancholvanich et al. [26]	PSI®	IRM	Scout-view	40	100	–	–	100	–
Present series	Knee-Plan®	CT	Matching CT	107	94	71	88	93	70

CAS: computer-assisted surgery

investigating other custom cutting-guide systems. Conteduca et al. [21] report acceptable results in the frontal plane but a 50% outlier rate within ±3 for tibial slope. Heyse et al. [22] concluded in a decrease in outliers for femoral rotation with custom cutting guides (2.2%) compared to conventional instrumentation (22.9%). With CAS, Lustig et al. [23] found unsatisfactory precision in the sagittal plane (65% of the patients within ±3) and transverse plane (77% within ±3). Roh et al. [24] did not report a significant difference in terms of alignment between conventional instrumentation and custom cutting guides, but abandoned the procedure with custom guides in 16% of the cases because of intraoperative inconsistencies in femoral rotation and tibial slope. Victor et al. [25] did not report a significant contribution of custom cutting guides compared to conventional instrumentation for the femoral component, and even an increase in the number of outliers for the tibial component (15% vs 3% in the frontal plane, 21% vs 3% in the sagittal plane). Chareancholvanich et al. [26] reported greater precision for custom cutting guides compared to conventional instrumentation (100% vs 82.5% for the femur and 100% vs 97.5% for the tibia, in the frontal plane) but with a postoperative verification on the CT scout-view.

In this series, the reproducibility of positioning was satisfactory for the frontal alignments (94% within ±3 for the femur and 93% within ±3 for the tibia), and for the sagittal and transverse position of the femoral component (respectively, 71% and 88% within ±3). The posterior tibial slope remains, as many authors have reported for all techniques, the most difficult parameter to

control (70% within ±3), but the design of the tibial guide has undergone successive improvements since this series and the most recent measurements show improved control of tibial slope.

The clinical and functional results, in terms of quality of life and activity, were also satisfactory, with significant improvement in the IKS score, knee flexion, the WOMAC score, and the level of activity compared to the preoperative condition. These values are comparable to the results observed earlier in our department, with the same operators, the same implant, and conventional instrumentation.

The reliability of the custom cutting guides could open the way to greater optimization and rationalization of the surgery, through entirely disposable instrumentation for knee arthroplasty. This experience with the Knee-Plan® system has also resulted in a new and more detailed way of considering knee morphotypes.

The limits of this study stem from its non-comparative design: these results must be compared to conventional instrumentation and CAS within a prospective and randomized three-arm trial. The clinical results over the longer term, as well as the data in terms of cost and surgical time should also be analyzed.

5. Conclusion

The Knee-Plan® system, which associates patient-specific 3D preoperative planning and custom cutting guides, may be a realistic, simple, and reliable alternative to conventional instrumentation and intraoperative CAS for implanting total knee prostheses.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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